GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:6404
ANSWERED ON:07.05.2003
DRUG LICENSING POWERS
MANSINH PATEL;RAM TAHAL CHOUDHARY

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the rules and regulations on existing drug licensing power at present;

(b) whether the Government propose to take away the drug licensing powers currently vested with the States;

(c) if so, whether this proposal for centralized licensing system for both the drug manufacturing and trade alongwith a Central vigilance system would help to solve many of the regulatory issues;

(d) if so, the details thereof; and

(e) the steps taken to implement this proposal?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a): Licensing of drug manufacture and sales establishments is governed by the provisions of Drugs and Cosmetic Rules, 1945 as amended from time to time. Under the rules, license for manufacture and sale of drugs is granted by the concerned State Licensing Authorities. Approval of new drugs is accorded by office of Drugs Controller General (India) based on which manufacturing license can be granted by State Licensing Authorities. For certain categories of drugs like vaccine and sera, large volume Parenterals (LVP) and Blood Bank/Blood Products, the license to manufacture are approved by Central License Approving Authority(CLAA).

(b): There is no such proposal at present.

(c)&(d): Due to lack of uniformity of enforcement and inadequacy of drug regulatory infrastructure in many states a view has been expressed at various fora that the licencing system for the manufacture of drugs in the country may be centralized so as to ensure uniform levels of GMP compliance and checks on drug formulations.

(e): An Expert Committee headed by Dr. R.A. Mashelker, DG, CSIR has been constituted to examine, inter-alia related to the structure of the Drug Regulatory System in the country and strengthening of the drug regulatory infrastructure in Centre and States.